

§170.315(e)(2) Secure messaging

2015 Edition CCGs

Version 1.2 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-22-2015
1.1	Revised to indicate this certification criterion is in scope for the Certified EHR Definition.	01-05-2016
1.2	Added clarification for time-limited certification to this criterion per the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule.	06-15-2020

Regulation Text

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§170.315 (e)(2) *Secure messaging*—

Enable a user to send messages to, and receive messages from, a patient in a secure manner.

Standard(s) Referenced

Please refer to the standards required for the 2015 Edition [Trusted connection](#) certification criterion.

Certification Companion Guide: Secure messaging

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key

portions of the rule’s preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

[Link to Final Rule Preamble](#)

Edition Comparison	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(e)(2). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(e) “paragraph (e)” criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (e) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be presented once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “VDT” and (e)(2) “secure messaging,” which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
 - [Authentication, access control, and authorization \(§ 170.315\(d\)\(1\)\)](#)
 - [Auditable events and tamper-resistance \(§ 170.315\(d\)\(2\)\)](#)
 - [Audit reports \(§ 170.315\(d\)\(3\)\)](#)
 - [Automatic access time-out \(§ 170.315\(d\)\(5\)\)](#)
 - [Trusted Connection \(§ 170.315\(d\)\(9\)\)](#) must be explicitly demonstrated with this criterion.
- If choosing Approach 2:
 - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion (with the exception of (§ 170.315(d)(9)) using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- [Quality management system \(§ 170.315\(g\)\(4\)\)](#)
- [Accessibility-centered design \(§ 170.315\(g\)\(5\)\)](#)

Technical Explanations and Clarifications

Applies to entire criterion

Technical outcome – A user can send messages to, and receive messages from a patient in a secure manner.

Clarifications:

- There is no standard required for this certification criterion.
- A Health IT Module presented for certification to this criterion must be separately tested to the privacy and security criterion for “trusted connection” at § 170.315(d)(9). [see also [80 FR 62707](#)]
- A health IT developer can choose between message-level or transport-level “trusted connection” certification in accordance with § 170.315(d)(9). [see also [80 FR 62661](#)]
- The encryption requirements of this certification criterion only apply to the message content and not to the patient’s device(s). [see also [80 FR 62661](#)]
- This criterion is not eligible for gap certification as the new hashing standard (a hashing algorithm with a security strength equal to or greater than SHA-2) applies to this criterion per the standard required at § 170.210(c)(2). [see also [80 FR 62661](#)]
- Secure email, a secure portal, even some type of mobile application could all be examples for secure messaging methods that could potentially meet this certification criterion. [see also [77 FR 54193](#)]
- We will test that the health IT has the capability as a whole to send and receive secure messages for certification in order for providers to have assurance that health IT can enable bidirectional communication. [see also [77 FR 54194](#)]
- As noted in Annex A: FIPS 140-2, only encryption and hashing algorithms are in scope for this certification criterion. Random number generator standards are not in scope. [see also [77 FR 54194](#)]
- ONC-ACBs will be permitted to issue certificates for this criterion up until January 1, 2022 to align with the requirements of the CMS Medicaid Promoting Interoperability Program. [see also [84 FR 42592](#)] We have included a provision in § 170.550(m)(1) to only allow ONC-ACBs to issue certificates for this criterion until January 1, 2022. Limiting certificates to this criterion for this period will help spur further innovations in patient engagement while helping to reduce regulatory burdens and costs for health IT developers and health care providers. Other 2015 Edition criteria better support interoperability and innovation in patient engagement. [see also [80 FR 25622](#)]

Content last reviewed on June 23, 2020